

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Atty Dkt. 2818-72

C# M#

DE SIMONE

TC/A.U.

1651

Serial No. 10/024,199

Examiner: Ware

Filed: December 21, 2003

Date: February 27, 2004

Title: COMBINATION OF LACTIC ACID BACTERIA AND ITS USE FOR THE  
PREVENTION AND/OR TREATMENT OF INFECTIONS AND INFLAMMATORY  
CONDITIONS

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**RESPONSE/AMENDMENT/LETTER**

This is a response/amendment/letter in the above-identified application and includes an attachment which is hereby incorporated by reference and the signature below serves as the signature to the attachment in the absence of any other signature thereon.

☒ **Correspondence Address Indication Form Attached.****Fees are attached as calculated below:**

|  |    |                      |              |         |
|--|----|----------------------|--------------|---------|
| Total effective claims after amendment | 0  | minus highest number |              |         |
| previously paid for                    | 20 | (at least 20) =      | 0 x \$ 18.00 | \$ 0.00 |

|                                    |   |                      |              |         |
|------------------------------------|---|----------------------|--------------|---------|
| Independent claims after amendment | 0 | minus highest number |              |         |
| previously paid for                | 3 | (at least 3) =       | 0 x \$ 86.00 | \$ 0.00 |

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| If proper multiple dependent claims now added for first time, add \$290.00 (ignore improper) | \$ 0.00 |
|--|---------|

|  |         |
|--|---------|
| Petition is hereby made to extend the current due date so as to cover the filing date of this paper and attachment(s) (\$110.00/1 month; \$420.00/2 months; \$950.00/3 months) | \$ 0.00 |
|--|---------|

|   |         |
|---|---------|
| Terminal disclaimer enclosed, add \$ 110.00 | \$ 0.00 |
|---|---------|

|   |         |
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| <input type="checkbox"/> First/second submission after Final Rejection pursuant to 37 CFR 1.129(a) (\$770.00) | \$ 0.00 |
|---|---------|

|   |  |
|---|--|
| <input type="checkbox"/> Please enter the previously unentered, filed |  |
|---|--|

|  |  |
|--|--|
| <input type="checkbox"/> Submission attached |  |
|--|--|

|                 |                |
|-----------------|----------------|
| <b>Subtotal</b> | <b>\$ 0.00</b> |
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|   |          |
|---|----------|
| If "small entity," then enter half (1/2) of subtotal and subtract | -\$ 0.00 |
|---|----------|

|  |   |
|--|---|
| <input type="checkbox"/> Applicant claims "small entity" status. | <input type="checkbox"/> Statement filed herewith |
|--|---|

|  |         |
|--|---------|
| Rule 56 Information Disclosure Statement Filing Fee (\$180.00) | \$ 0.00 |
|--|---------|

|                                    |         |
|------------------------------------|---------|
| Assignment Recording Fee (\$40.00) | \$ 0.00 |
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| Other: | 0.00 |
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|---------------------------|----------------|
| <b>TOTAL FEE ENCLOSED</b> | <b>\$ 0.00</b> |
|---------------------------|----------------|

The Commissioner is hereby authorized to charge any deficiency, or credit any overpayment, in the fee(s) filed, or asserted to be filed, or which should have been filed herewith (or with any paper hereafter filed in this application by this firm) to our Account No. 14-1140. A duplicate copy of this sheet is attached.

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NIXON & VANDERHUYE P.C.  
By Atty: Arthur R. Crawford, Reg. No. 25,327

Signature: \_\_\_\_\_



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Patent Application of

DE SIMONE

Atty. Ref.: 2818-72; Confirmation No. 4379

Appl. No. 10/024,199

TC/A.U. 1651

Filed: December 21, 2001

Examiner: Ware

For: COMBINATION OF LACTIC ACID BACTERIA AND ITS USE FOR THE  
PREVENTION AND/OR TREATMENT OF INFECTIONS AND  
INFLAMMATORY CONDITIONS

\* \* \* \* \*

February 27, 2004

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**RESPONSE**

Responsive to the Official Action dated December 16, 2003 in which claims 23-41 are rejected on the basis of prior art of record as well as two newly cited references. The reviewed claims were presented in an Amendment filed October 29, 2003, and while the claims have been examined, there is no rebuttal provided to the arguments and comments submitted at the same time these claims were presented. Instead, newly cited documents have been brought forward.

Claims 23-41 are rejected under 35 USC §103(a) as being unpatentable over newly cited Cavaliere Vesely et al (A) in view of previously cited of record Cavaliere Ved. Vesely et al, and Ehret and newly cited Dobrogosz et al (B). The arguments in support of the rejection put forward on pages 2 and 3 of the Official Action are not consistent with the content of the documents themselves and would instead appear to be a

selection/"picking and choosing" more driven by the content of the claims under examination.

The newly cited Vesely et al. is not pertinent to the claims now under review nor is it rationally combined with the other citations.

Even if Vesely '104 is combined Vesely '370 and Ehret (applicant contends this is improper), the newly cited Vesely '104 provides no guidance at all to the invention defined in applicant's claims 23-41. It will be noted that the passage cited by the Examiner, col. 5, lines 33-35 does not contribute to the building of the claimed invention. In the reference the lactic acid bacteria can be combined with "a **drug compatible** with the bacteria employed and capable of potentiating the activity of the active ingredients present". (Emphasis added.)

First, the skilled person has to determine what active ingredient and which activity will be potentiated, then with what. On column 2, last paragraph, the skilled person will discover that the active ingredient is lactic acid bacteria selected from the group consisting of *Streptococcus thermophilus* and *Lactobacillus bulgaricus*. None of these strains are claimed in the present main claims.

Then, the skilled person will learn from the same passage of the cited reference that the strains *Streptococcus thermophilus* and *Lactobacillus bulgaricus* exhibit (a) a 7 $\alpha$ -dehydroxylase activity of less than 50% and (b) a bile acid deconjugation activity of less than 50%. This activity is neither H<sub>2</sub>O<sub>2</sub>-producing activity nor arginine-deiminase activity. The diseases treated in Vesely '104 are the ones associated with or caused by a **metabolic disorder of the biliary acids**.

Finally, in the newly cited reference the activity of the lactic acid bacteria strains is potentiated with a drug, not with another lactic acid bacteria strain.

Thus, the skilled person, finding a solution to the problem of treating infections and inflammatory conditions caused by bacteria, viruses or fungi, especially in the mouth, vagina, urethra, nose, eyes and ears, would disregard this reference, simply because it is of no help.

Dobrogosz et al. disclose strains of *Lactobacillus reuteri* producing the antibiotic reuterin.

Applicant respectfully submits that the conclusions resulting from the Examiner's reasoning is erroneous. For the reasons of record, the skilled person would not have substituted the bacteria and drug disclosed by US '104 with the allegedly suggested combination of US '370 and Ehret, because there is no suggestion in the art to substitute a lactic acid bacteria strain selected from the group consisting of *Streptococcus thermophilus* and *Lactobacillus bulgaricus* and exhibiting (a) a 7 $\alpha$ -dehydroxylase activity of less than 50% and (b) a bile acid deconjugation activity of less than 50%, said strain being potentiated with a drug, with a H<sub>2</sub>O<sub>2</sub> producing lactic acid bacteria strain, the strain being potentiated with an arginine-utilizing lactic acid bacteria strain. Moreover, US '370 and Ehret cannot be combined for the reasons already of record.

US '104 arrives at treating conditions different from the ones treated by the present invention, and the means of treatment are also different.

There is no suggestion to substitute the Dobrogosz strain with the combination of the present invention.

The present invention does not claim to have found new strains, since the activity of H<sub>2</sub>O<sub>2</sub> producing lactic acid bacteria strain is acknowledged in the present invention (see page 1, third paragraph), but in the methods defined claims the potentiating effect of this activity brought about by arginine-utilizing strains.

Applicant maintains his previously stated position, as the U.S. Court of Appeals for the Federal Circuit has stated that "[t]he mere fact that the prior art may be modified in the manner suggested by the examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992) (citing *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984)). Similarly, the Board of Appeals and Interferences, in a non-precedential decision (67 USPQ2d 1633 at 1635) held that the mere fact that teachings found in the prior art could be combined as proposed by an

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examiner does not make the combination obvious "absent some teaching, suggestion or incentive supporting the combination." *Carella*, 804 F.2d at 140, 231 USPQ at 647 (citing *ACS Hosp. Sys., Inc.*, 732 F.2d at 1577, 221 USPQ at 933).

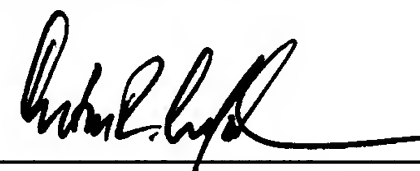
Even assuming *arguendo* the four documents may be combined (applicant does not agree to this), there still is no reasonable assurance in the art that peroxide-producing lactic acid bacteria could be potentiated in activity by employing an arginine-utilizing lactic acid bacteria – in other words, there is no expectation that the combination of disclosures would result in the method defined by applicant's claims either in potentiating the activity of peroxide-producing lactic acid bacteria or for providing an effective way of preventing or treating infections or inflammatory conditions as featured in claims 38-41.

For the above reasons it is respectfully submitted that the claims of this application define inventive subject matter. Reconsideration and allowance are solicited.

Respectfully submitted,

**NIXON & VANDERHYE P.C.**

By: \_\_\_\_\_

  
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